

REMARKS

Claims 14-33 are pending in this application. Claims 1-13 have been canceled. Claims 14-33 have been added.

The Office Action of August 24, 2004 presents the examination of claims 1-13. These claims are canceled, being replaced by new claims 14-33 directed to the same subject matter. This method of amendment was chosen for its editorial simplicity.

Information Disclosure Statement

Applicants note that the Examiner has crossed through some of the references listed on the IDS form PTO-1449 filed previously. Except for the Kigawa reference, the crossed through references are foreign language equivalents of U.S. patents that were included among the references filed and were considered.

Drawings

The Examiner has objected to Figure 4 as not being legible. Applicants provide herewith a reprinted Figure 4. The specification is also amended to better describe what is depicted in Figure 4. The amendments to the specification do not add any new matter to the application; the new text is supported by the original disclosure at page 23 and the drawing Figure 4.

Claim objections

The Examiner objects to claim 2 in the recitation of "primer dimmer", lack of indefinite articles and use of the term "coding". These formal matters are addressed by Applicants' amendments to the claims herein.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 1-13 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite for a number of reasons as set forth on page 3-6 of the Office Action. Claims 1-13 are canceled rendering this rejection moot. Applicants have amended the claims to address the problems pointed out by the Examiner and therefore this rejection should not be applied to the now pending claims.

However, Applicants traverse this rejection to the degree that it is grounded on the use of the word "terminal" as 5' or 3' terminal regions of a nucleic acid. The word "terminal", including a degree of overlap of sequences, is defined in the specification at page 8.

Regarding the supposed "partial invention" set forth in claim 1, Applicants have presented new claim 14 directed to the same subject matter. Applicants submit that the first PCR reaction produces an intermediate that can either be subjected to transcription/translation *in vitro*, for example if the first DNA fragment includes sufficient regulatory sequences from a genomic

clone, or that can be used in the second PCR reaction as described in the present claims 15 and 17. In this regard, Applicants direct the Examiner's attention to Example 1. The DNA fragment of this example, T7P (one of SEQ ID NOs: 6 to 10) includes a tag sequence downstream from and operatively-linked to a T7 promoter and a ribosome binding (Shine-Delgarno) sequence.

Rejections over prior art

Claim 13 is rejected under 35 U.S.C. § 102(b) as anticipated by Sheikh et al., WO 97/46696. Claim 13 is canceled, rendering this rejection moot. To the degree that the present claims reflect the subject matter of claim 13, the rejection is traversed.

The Examiner's position is that the method for producing the template used in the claimed *in vitro* protein synthesis process is not relevant. While the Examiner might be correct that, as to a claim to a DNA template itself, the method steps used to produce the template would be irrelevant for examination, that is not the case for process claims such as the instant claims.

For a reference to anticipate a claim it must disclose, either expressly or inherently, each limitation recited in the claim. See, e.g. *Verdegaal Bros. V. Union Oil Co. of California*, 2 USPQ2d 1051,1053 (Fed. Cir. 1987). In the context of process claims, such as the instant claims, this means that each step of the claimed process, with all of the limitations thereof, must be considered.

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The present claims include some that recite steps for preparing a template to be used in a PCR reaction. See, e.g. claim 17 in its part ii). A recitation of a step of how the template is prepared is a relevant limitation in these claims that must be considered when comparing the instant claims to the Sheikh reference.

Claims 1-11 and 13 are rejected under 35 U.S.C. § 102(e) as being anticipated by Endo et al., US Publication 2004/0121346 A1. These claims have been canceled, rendering this rejection moot. Applicants submit that the rejection should not be applied to the pending claims.

The Endo '346 publication is not a reference citable as prior art under 35 U.S.C. § 102(e). The PCT application from which the publication stems was filed August 28, 2001 and was published in Japanese. For a U.S. patent application publication to be citable as prior art under 35 U.S.C. § 102(e), the application must have been filed prior to November 29, 2000 and completed the requirements of 35 U.S.C. § 371(a)-(d), or if filed later, must have been published in English and designated the United States for national stage entry. The Endo '346 publication stems from an application meeting neither of these sets of conditions, and so is

not citable as prior art under 35 U.S.C. § 102(e). MPEP 706.02. Accordingly, the instant rejection should be withdrawn.

English translation of priority document

Applicants have noticed that the Endo '346 publication cites as a priority application JP 2000-261638. A publication of this application may be prior art under 35 U.S.C. § 102(a) to the present application. Applicants thus attach hereto a verified English translation of JP 2001-201356, filed July 2, 2001, which is the priority document of the present application.

Conclusion


Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Mark J. Nuell (Reg. No. 36,623) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Applicant submits that the present application well-describes and claims patentable subject matter. Accordingly, the favorable actions of withdrawal of the standing rejections and allowance of the pending claims are respectfully requested.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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Attachment(s): Figure 4 (Replacement Sheet)
and verified English translation of JP 201-201356.

AMENDMENTS TO THE DRAWINGS

Attached hereto is one (1) sheet(s) of corrected formal drawing that complies with the provisions of 37 C.F.R. § 1.84. The corrected formal drawings incorporate the following drawing changes:

The Examiner has objected to Figure 4 as not being legible. Applicants provide herewith a reprinted Figure 4 (replacement sheet showing Figure 4).

It is respectfully requested that the corrected formal drawings be approved and made a part of the record of the above-identified application.